DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 7, 2014

Vatech Co., Ltd.
% Mr. David Kim
Medical Device Regulatory Affairs
Mtech Group
8310 Buffalo Speedway
HOUSTON TX 77025

Re: K132983
Trade/Device Name: TON-95LH and PaX-i3D Ortho
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: July 7, 2014
Received: July 9, 2014

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132983

Device Name
PaX-i3D Ortho (TON-95LH)

Indications for Use *(Describe)*

PaX-i3D Ortho (TON-95LH) is a computed tomography x-ray system intended to produce cross-sectional images of the oral anatomy by reconstructing a three dimensional radiographic images from the same axial plane taken at different angles. It provides diagnostic details of the maxillofacial areas for a dental treatment in adult and pediatric dentistry. The system also acquires carpal images for orthodontic treatment. The device is operated and used by physicians, dentists, and x-ray technicians.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Traditional 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date 510K summary prepared: July 7th, 2014

Submitter's Name, address, telephone number, a contact person:

Submitter's Name :	Vatech Co., Ltd.
Submitter's Address:	23-4, Seogu-Dong, Hwaseong-Si, Gyeonggi-Do, 445-170, Republic of Korea
Submitter's Telephone:	+82-31-379-9492
Contact person:	Mr. Daniel Kim
Official Correspondent:	Dave Kim **(**davekim@mtech-inc.net**)**
(U.S. Designated agent)	
Address:	8310 Buffalo Speedway, Houston, TX 77025
Telephone:	+1- 713-467-2607
Fax:	+1- 713-583-8988

Name of the device, including the trade or proprietary name if applicable, the common or usual name and the classification name, if known:

Trade/Proprietary Name:	PaX-i3D Ortho (TON-95LH)
Common Name:	Dental Computed Tomography X-ray System
Classification Name:	System, X-ray, Tomography, Computed , Dental(21CFR 892.1750, Class II)
Product Code:	OAS

Predicate Device:

Manufacturer:	Vatech Co., Ltd
Device Name:	PaX-Zenith3D
510(k) Number:	K102196

Device Description:

PaX-i3D Ortho (TON-95LH) is a dental radiographic imaging system with cone beam computed tomography (CBCT) to offer high definition digital diagnostic images in multi FOV for dental practitioners. Specifically designed for dental radiography of the teeth or jaws, TON-95LH is a complete dental X-ray system equipped with x-ray tube, generator and dedicated SSXI detector for dental CBCT radiography.

The PaX-i3D Ortho (TON-95LH) dental CBCT system is equipped with a CMOS digital X-ray detector which is used to capture radiographic diagnostic image data of oral and maxillofacial anatomy and reconstruct a three dimensional (3D) image for dental treatments such as oral surgery, implant and orthodontic. The PaX-i3D Ortho (TON-95LH) dental CBCT system also can reconstruct 2D panoramic and cephalometric images from the same diagnostic image data which the system originally obtained.

Indication for use:

PaX-i3D Ortho (TON-95LH) is a computed tomography x-ray system intended to produce cross-sectional images of the oral anatomy by reconstructing a three dimensional radiographic images from the same axial plane taken at different angles. It provides diagnostic details of the maxillofacial areas for a dental treatment in adult and pediatric dentistry. The system also acquires carpal images for orthodontic treatment. The device is operated and used by physicians, dentists, and x-ray technicians.

Summary of the technological characteristics of the device compared to the predicate device:

The PaX-i3D Ortho (TON-95LH) dental CBCT system described in this 510(k) has the similar intended use and technical characteristics as PaX-Zenith3D of Vatech Co.,Ltd.

Characteristic	**Proposed** **Vatech Co., Ltd.** **PaX-i3D Ortho (TON-95LH)**	**Predicate** **Vatech Co., Ltd.** ***PaX-Zenith3D***
510(k) number	K132983	K102196

Indications for use	PaX-i3D Ortho (TON-95LH) is a computed tomography x-ray system intended to produce cross-sectional images of the oral anatomy by reconstructing a three dimensional radiographic images from the same axial plane taken at different angles. It provides diagnostic details of the maxillofacial areas for a dental treatment planning in adult and pediatric dentistry. The system also utilizes carpal images for orthodontic treatment. The device is operated and used by physicians, dentists, and x-ray technicians.	PaX-Zenith3D is a computed tomography x-ray system intended to take panoramic, cross-sectional images of the oral and craniofacial anatomy and provide diagnostic information for children and adults clinical care in dentistry. The device is operated and used by x-ray technicians and dentists including oral surgeons.
Performance Specification	computed tomography	Panoramic and computed tomography
Input Voltage	AC 100-240 V	110V/230 V~
Tube Voltage	50-120 kV	50-120 kV
Tube Current	4 ~10 mA	4 ~10 mA
Exposure Time	Max. 24 s	9.7s-24 s
X-ray Source	SXR-130-15-0.5	SXR-130-15-0.5
X-ray Generator	DG-08B11S1	EXG8
Focal Spot Size	0.5 mm	0.5 mm
Slice Width	0.1 mm min.	0.1 mm min.
Total Filtration	2.8 mmAl	2.8 mmAl
Chin Rest	Equipped Headrest	Equipped Headrest
Performance Specification	Computed tomography	Computed tomography
Mechanical	Compact design	Compact design
Electrical	LDCP logic circuit	LDCP logic circuit
Software	DICOM 3.0 Format compatible	DICOM 3.0 Format compatible
2D Image Viewing Program	EzDent-i	EasyDent

3D Image Viewing Program	Ez3D-i Ortho	Ez3D Plus
Anatomical Sites	Maxillofacial	Maxillofacial
Image Receptor (*CMOS photodiode array)*	CT- Xmaru2430CF Master Plus	CT- Xmaru2430CF
	-	Panoramic- Xmaru1501CF
Size of Active Imaging Area	CT- 289.4 x 230.8 mm	CT- 288 x 238.4 mm
	-	Panoramic- 150.4 x 6 mm
Pixel Resolution	CT- 5 lp/mm -2x2 binning 2.5 lp/mm -4x4 binning	CT- 2.5 lp/mm
	-	Panoramic- 5 lp/mm
Pixel Size	CT- 99 μm-2x2 binning 198 μm-4x4 binning	CT- 200 μm
	-	Panoramic- 100 μm

Summary of Performance Testing:

The PaX-i3D Ortho (TON-95LH) dental CBCT system described in this 510(k) is similar to the predicate device in its indications for use, materials, safety characteristics, X-ray source.

Moreover, the following information further substantiates the substantial equivalence between two devices:

The fundamental technological characteristics of the subject and predicate device are the same.

Laboratory and clinical performance testing using the same test protocols as used for the cleared detectors was evaluated by qualified individuals employed by the

sponsor to demonstrate that adequate design controls (according to 21 CFR 820.30) were in place.

For both devices, the differences are as follows.
A new SSXI detector, Xmaru2430CF Master Plus for PaX-i3D Ortho (TON-95LH) has different active areas compared with PaX-Zenith3D (K102196), the predicate device.
Change to Free Input Voltage: For the predicate device, changing the input voltage from 110V to 230V would require separate tools and electrical works whereas the new device is equipped with a new power board which is capable of handling the input power between 100 V and 240 V without a separate tool or electrical modification.

Non-clinical test and clinical consideration test were conducted for the PaX-i3D Ortho (TON-95LH) system's new sensor and compared with the predicate device with regard to Modulation Transfer Function (MTF), Detective Quantum Efficiency (DQE) and Noise to Power Spectrum (NPS). Based on the Non-Clinical Test results, even though the new SSXI detector differs in term of the pixel size and active area, the diagnostic image quality of the new sensor is equal or better than those of the predicate device and there is no significant difference in efficiency and safety.

Safety, EMC and Performance Data:
Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1(A1+A2, 1995), IEC 60601-1-1 (Ed. 2, 2000), IEC 60601-1-3 (Ed. 1, 1994), IEC 60601-2-7 (Ed. 2, 1998), IEC 60601-2-28 (Ed. 1, 1993), IEC 60601-2-32 (Ed. 1, 1994) and IEC 60601-2-44 (Ed. 2, 2002) were performed, and EMC testing were conducted in accordance with standard IEC 60601-1-2.

The manufacturing facility is in conformance with the relevant EPRC standards as specified in 21 CFR 1020.30, 31, and 33 and the records are available for review.

PaX-i3D Ortho (TON-95LH) meets the provisions of NEMA PS 3.1-3.18, Digital Imaging and Communications in Medicine (DICOM) Set.

Non-clinical & Clinical considerations according to FDA Guidance "Guidance for the submissions of 510(k)'s for Solid State X-ray Imaging Devices" were performed.

Acceptance test and CT image evaluation report according to IEC 61223-3-4 and IEC 61223-3-5 were performed.

All test results were satisfactory.

Conclusion:
In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification. Vatech Co., Ltd. concludes that PaX-i3D Ortho (TON-95LH) is safe and effective and substantially equivalent to the predicate device as described herein.

END